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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,692	11/24/1999	ARTHUR ASHMAN	1527/0E847-U	5329

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EXAMINER
ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/448,692	ASHMAN, ARTHUR	
	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-3,5-20,22-34 and 36-88* is/are pending in the application.

4a) Of the above claim(s) *22-34,36-49 and 66-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20,50-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election with traverse of group 1 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search is not a serious burden on the examiner even though the claims are directed to independent invention. This is not found persuasive because the criteria of a "serious burden" is not a basis of the restriction. The basis of the restriction is based upon the concept of independent inventions. Applicant should be reminded that a restriction may be required at any point in the prosecution of an application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-34,36-49 and 66-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims1-3,5-20,50-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 as worded is confusing and therefore, indefinite. The claim is directed to an intermediate product of polymeric particles with a coating thereon. This intermediate product is of no form or unitary body. Moreover, these particles are not

incorporated into a matrix material as described in the specification. It appears that the intermediate product as claimed (as supported by the specification) is nothing more than disjointed particles. Therefore, it is not clear how the disjointed particles form a dimension to permit soft tissue growth therein.

Claim 1, the term "intraparticulate" does not find support in the specification as filed.

Claim ~~6~~ 5 is indefinite. The range cannot be correct. If there is zero percent pore volume then there is no porosity in the material.

Claim 9 is indefinite. It is not clear how the material further comprises collagen. Is the collagen part of the polymer matrix or is the collagen a separate entity?

Claim 12 is indefinite. It is not clear what is meant by "injectable collagen".

Claim 13 is indefinite. There is no nexus between the elements of claim 20 and claim 13. It is not clear if the polymeric particles have an inner and outer layer and an additional hydrophilic layer or if the hydrophilic layer is the calcium hydroxide.

Claim 18, it is not clear how the bioactive element is added to the polymeric particles. There is no physical nexus between the particles of claim 20 and the bioactive element.

Claim 19, see rejection to claim 18 supra.

Claim 50 is indefinite. The claim fails to further define the material of claim 20. Claim 20 defines an implant material. It is not clear how the "implant" of the preamble of claim 50 further defines the structure of the implant material of claim 20.

Claim 51, see rejection to claim 20 supra.

Claim 52, see rejection to claim 1 supra.

Claim 53, see rejection to claim 6 supra.

Claim 59, see rejection to claim 9 supra.

Claim 62, see rejection to claim 12 supra.

Claim 63, see rejection to claim 18 supra.

Claim 65, see rejection to claim 50 supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruins, et al.

An implant comprising particles having an inner core of PMMA and an outer layer of PHEMA is fully disclosed by Bruins. Note, that the claims are readable on the intermediate product as disclosed by Bruins. The particulars directed to the pore size and volume are disclosed by Bruins, et al.

Bruins, et al specifically recognizes the requirements for soft tissue ingrowth in to the pores and these parameters have been disclosed in 1985.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,5-20, 50-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek, et al (5,336,263) in view of Ashman ('570).

Ersek, et al discloses a particulate soft tissue implant comprising every element as claimed except for the coating of calcium hydroxide. To coat the PMMA particles of Ersek, et al with calcium hydroxide to stimulate healing by reducing infections and stimulating new tissue formation would have been obvious from the teachings of Ashman. The particulars to the pore size and volume is fully disclosed by Ersek, et al. The limitations directed to the collagen is disclosed in columns 3 and 4 of Ersek, et al.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that the reference to Bruins is directed to a fused material. Applicant should note, for the record, that claim 20 as amended does not preclude an implant with fused particles. Moreover, the claim, if interpreted as particulates, fails to define over the intermediate product as disclosed by Bruins. Also note, the preamble of the claim is more particularly directed to an intermediate product (ie material) as opposed to an implant.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

dji
April 2, 2002